**AWARD NUMBER:** W81XWH-15-1-0470

**TITLE**: The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited Community Ambulators

**PRINCIPAL INVESTIGATORS:** Dr. Audrey Zucker Levin

CONTRACTING ORGANIZATION: University of Tennessee
Memphis, TN 38163

**REPORT DATE:** September 2017

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*



| 1. REPORT DATE | 2. REPORT TYPE | 3. DATES COVERED |
|---|---|---|
| September 2017 | Annual | 01 Sep 2016 - 31 Aug 2017 |

**4. TITLE AND SUBTITLE**
The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited Community Ambulators

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-15-1-0470

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**
Audrey Zucker-Levin, PhD, PT, GCS Emeritus (Joint-PIs);and

Phyllis A. Richey, PhD

E-Mail: prichey@uthsc.edu

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

UNIVERSITY OF TENNESSEE
62 S DUNLAP STREET RM 300
MEMPHIS TN 38103-4903

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6-month period of time in addition to receiving physical therapy training. All outcome measures will be evaluated three times during the 6 month study period. Once HRPO approval for the project was received in April 2016, recruitment efforts via Partner Prosthetic clinics was undertaken to identify over 700 potentially eligible individuals, 40 of whom were veterans. Similar efforts with the Regional DAV have also been undertaken. Active recruitment began in July 2016 and has yielded 77 individuals responding to recruitment efforts, 76 of whom have been screened for eligibility. Of those, 32 (42%) met eligibility criteria to qualify for evaluation of Medicare Functional Classification Level (MFCL) using the Amputee Mobility Predictor-Prosthesis (AMP-Pro). Five (15.6%) of those individuals (who comprised 7% of the total 76 screened) met the K-Level 2 classification as a "community ambulator" and were eligible for randomization to group assignment. Recruitment, enrollment/randomization, intervention and followup assessments will continue in the coming quarter/year.

**15. SUBJECT TERMS**
Trans-tibial amputee (TTA), microprocessor controlled prosthetic foot (MPF), randomized clinical trial, functional performance, ambulatory safety, falls, quality of life, community ambulator

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
|---|---|---|---|---|---|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | USAMRMC |
| Unclassified | Unclassified | Unclassified | UU | 18 | 19b. TELEPHONE NUMBER *(include area code)* |

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**Page No.**

1. **INTRODUCTION:**

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. The blocked randomization schedule will be generated by a computer program with a block size of 4; this will guarantee that we have approximately the same number of participants in each treatment group throughout the trial. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6 month period of time and receive physical therapy training to minimize deviations resulting from habit or lack of training, education to maximize use of the mechanical properties of their current foot, strengthening and stretching based on published guidelines for TTA, balance training and training on traversing environmental barriers. All outcome measures will be evaluated three times during the 6 month study period: At baseline, at the 3-month follow up visit and at the 6 month follow up visit. We believe the immediate benefit of this project will determine if an innovative MPF, designed to facilitate toe clearance by optimizing ankle angle and foot position, will improve functional performance, ambulatory safety (risk of falls), and quality of life in the typical veteran amputee. This study will also have significant long term benefit for all typical amputees, both veterans and the general public, as they face medical, social and psychological complications associated with falling (broken bones, head trauma, depression, social isolation and death), decreased function and poor quality of life that directly impacting their families and caregivers.

2. **KEYWORDS:**

. Trans-tibial amputee (TTA)
Microprocessor controlled prosthetic foot (MPF)
Randomized clinical trial
Functional performance
Ambulatory safety
Falls
Quality of life
Community ambulator

3. **ACCOMPLISHMENTS:**

**What were the major goals of the project?**

The major goals of this project as stated in the approved SOW are as follows:

1. Perform Preliminary Study Requirements (Months 1-6)
2. Recruit, Coordinate and Train Study Personnel for Clinical Trial (Months 3-6)
3. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Baseline Randomization Evaluations (Months 7-24)
4. Participant Randomization (Months 7-24)
5. Participant Fit with Microprocessor Foot; Intervention Group (N=27; Months 7-24)
6. Physical Therapy Sessions and Prosthesis Accommodation Period (N=54; Months 7-24)
7. 3-Month Follow Up Visit and Prosthesis Accommodation Period (N=54; Months 10-27)
8. 6-Month Follow Up Visit and subject closure (N=54; Months 10-30)
9. Data Analysis/Dissemination of Findings (Months 28-36)
10. Assess Prosthesis related quality of life (N=54; Months 7-36)

**What was accomplished under these goals?**

1. Perform Preliminary Study Requirements
    a. Prepare study documents and apply for Local IRB (UTHSC) and USAMRM Human Research Protection Office (HRPO) approval- Complete, HRPO approval received Apr 5, 2016.
        - Updated consent form submitted Apr 26, 2016- Approved May 5, 2016
    b. Complete Manual of Operations finalizing procedures sections and forms for recruiting and reporting – completed May 2, 2016
    e. Develop database management system – completed May 26, 2016
    f. Develop and finalize all study data collection forms - May 2, 2016
    g. Submit amendments, adverse events and protocol deviations – In progress.
    h. Maintain, update and perform data integrity test on study DBMS – In progress.

2. Train Study Personnel for Clinical Trial
    a. Train staff, evaluation physical therapist, treating physical therapist and prosthetists for project – completed May 27, 2016
        - Trial run through of Screening and Baseline visits for the study
        - Eligibility and Randomization training – Completed March 31, 2016
        - Adverse Events Training with Dr. Mihalko, MD – Completed April 1, 2016
    b. Develop participant recruitment materials – completed May 13, 2016
        - Participant Flyer - Completed Mar 16, 2016
        - Participant Flyer with Tear-offs – Completed Mar 16, 2016
        - Business Card – Completed Mar 16, 2016

3. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit– In Progress
    a. Participant recruitment – In progress, have performed initial targeted recruitment via Partner Prosthetic clinics and have begun the same with Regional DAV, VA and local area hospitals, to identify targeted mailings to prospective participants.
        - Identify prospective participants for targeted recruitment
        - Perform phone (pre-) screening, schedule qualifying participants to baseline session – In Progress
    b. Confirm pre-screening at in person Screening Eligibility Visit – In Progress
        - Sign informed consent
        - Evaluate functional level of participant
        - Evaluate fit of current prosthesis
    c. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Evaluations – In Progress
    d. Baseline Randomization Evaluations – In Progress

4. Participant Randomization – In Progress

5. Participant Fit with Microprocessor Foot; Intervention Group – In Progress

6. Physical Therapy Sessions and Prosthesis Accommodation Period– In Progress

7. 3-Month Follow Up Visit and Prosthesis Accommodation Period- In Progress

8. 6-Month Follow Up Visit and subject closure- In Progress

**What opportunities for training and professional development has the project provided?**

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project.*

*"Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

During this reporting period we provided a 6 CEU professional development seminar for physical therapists and prosthetists in the Memphis area offered by Ossur trainers on April 18, 2017 at the University of Tennessee Health Science Center.

**How were the results disseminated to communities of interest?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

Nothing to Report

**What do you plan to do during the next reporting period to accomplish the goals?**
*If this is the final report, state "Nothing to Report."*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

During the next reporting period we will continue to perform the following actions to accomplish the goals and objectives listed:

1. Continue to perform ongoing study requirements
    a. Submit amendments, adverse events and protocol deviations as necessary
    b. Maintain, update and perform data integrity test on study DBMS
2. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit
3. Participant Recruitment
4. Identify prospective participants for targeted recruitment
5. Confirm pre-screening at in person Screening Eligibility Visit
    a. Sign Informed Consent
    b. Confirm pre-screening in person
    c. Perform screening evaluation including evaluation of functional level of participant
    d. Evaluate prosthetic fit
6. Participant Randomization
    a. Randomize participants into Intervention (N=27) or Comparison (N=27) Groups

b. Schedule visits for prosthetic clinics (Intervention group) and physical therapy visits

7. Participant Fit with Microprocessor Foot
    a. Provide participants randomized into Intervention group new prosthetic foot and train on use of foot during 2-4 prosthetic clinic over 2 week period

8. Physical Therapy Sessions and Prosthesis Accommodation Period 1
    a. Provide all participants 2 sessions per week of physical therapy for 4 weeks
    b. Provide weekly phone visits during 8-week accommodation period 1 to all participants in both groups

9. Perform 3-month evaluation and Prosthesis Accommodation Period 2
    a. Perform repeat of all baseline evaluation measures
    b. Provide weekly phone visits during 12-week accommodation period 2 to all participants in both groups

10. Perform 6-month evaluation and subject closure
    a. Perform repeat of all baseline evaluation measures
    b. Provide participants randomized into Intervention group prosthetic foot finishing of the Microprocessor foot or return and finish original prosthetic foot to participant

11. Begin data analysis of primary outcomes
    a. Mine data and prepare data sets for analyses
    b. Perform all analyses according to specifications, share output and findings with all investigators.

12. Begin data analysis of prosthesis-related quality of life outcomes
    a. Mine data and prepare data sets for analyses
    b. Perform all analyses according to specifications, share output and findings with all investigators

**4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

**What was the impact on the development of the principal discipline(s) of the project?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to Report

**What was the impact on other disciplines?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to Report

**What was the impact on technology transfer?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

**What was the impact on society beyond science and technology?**
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

**Changes in approach and reasons for change**
*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

Nothing to Report

**Actual or anticipated problems or delays and actions or plans to resolve them**
*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

During the current reporting period we experienced difficulty randomizing eligible participants due to an inclusionary criteria restriction. To date, 77 individuals have responded to our recruitment efforts, 76 of whom have been screened for eligibility. Of those, 32 (42%) met eligibility criteria to qualify for evaluation of Medicare Functional Classification Level (MFCL) using the Amputee Mobility Predictor-Prosthesis (AMP-Pro). Five (15.6%) of those individuals (who comprised 7% of the total 76 screened) met the K2-Level classification as a "community ambulator" and were eligible for randomization to group assignment. Our AMP-Pro results to date are presented in Table 1 below.

***Table 1: VALOR Study Frequency of participant MFCL by K-Level evaluated using the AMP-Pro***

| *K-Level* | *Frequency* | *Percent* |
|---|---|---|
| **K2** | 5 | 15.63% |
| **K3** | 14 | 43.75% |
| **K4** | 13 | 40.63% |
| **Total** | **32** | **100.00%** |

In light of the fact that our randomization of K2 participants is slower than we expected, despite our substantial efforts, and because we need a sample size of 54 individuals (27 intervention, 27 comparison) to detect a significant difference in our primary outcome measures of functional performance (using the Dynamic Gait Index), ambulatory safety (using the Four-Square Step Test) and quality of life (using the Orthotics and Prosthetics Users' Survey), we are formally requesting to broaden the inclusion criteria to also include amputees at the K3-Level.

Based on a sample size of 54, and utilizing the AMP-Pro results collected to date, we have determined that it will also be possible to detect a change of 4.2 points (p=0.05, 80% power) in Amp-Pro score for the total sample in addition to our primary outcomes. K3-Level individuals who are not currently wearing an MPF are believed to show significant benefit and improvement in our primary outcome measures similar to K2-Level individuals. We are currently in the process of obtaining IRB and HRPO approval for this inclusionary criteria adjustment and anticipate a dramatic increase in randomized participants allowing us to fulfill the target sample size as a result.

**Changes that had a significant impact on expenditures**
*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

As described above in actual delays during this reporting period, we experienced slower than expected randomization of K2-Level participants. Therefore, participant-related (e.g.

Partner Prosthetic clinic expenses, the Proprio MPF, participant incentives, etc). expenditures have been significantly lower than anticipated during this reporting period. However, as randomization increases during the coming reporting periods expenditures will adjust to those originally budgeted for this project.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

None

**Significant changes in use or care of vertebrate animals.**

Not Applicable

**Significant changes in use of biohazards and/or select agents**

Not Applicable

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Nothing to Report

- **Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

- **Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each*

*one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

- **Other publications, conference papers, and presentations**. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**
*List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

Nothing to Report

- **Technologies or techniques**
*Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.*

Nothing to Report

- **Inventions, patent applications, and/or licenses**
*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

Nothing to Report

- **Other Products**
*Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*
    - *data or databases;*
    - *biospecimen collections;*
    - *audio or video products;*
    - *software;*
    - *models;*

- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

During the current reporting period the study database has been expanded to enhance the informatics solution supporting the day-to-day management of the study.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**
*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."*

| | |
|---|---|
| Name: | Phyllis Richey, PhD |
| Project Role: | Joint-Principal Investigator |
| Research Identifier: | 1 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Dr. Richey is fulfilling the role of co-Principal Investigator and has also assumed most of Dr. Zucker-Levin's duties as of March 1, 2017 as outlined in the revised SOW submitted March 1, 2017. |

| | |
|---|---|
| Name: | Audrey Zucker-Levin, PhD, PT |
| Project Role: | Joint-Principal Investigator |
| Research Identifier: | 2 |
| Nearest person month worked: | 6 |
| Contribution to Project: | Dr. Zucker-Levin role has changed due to her leaving the full-time employment of the University March 1, 2017. She remains on the project contributing up to 10% effort with her previous duties being redistributed to Dr. Richey (Joint-PI) and Dr. Singhal (Co-I) as outlined in the revised SOW submitted March 1, 2017. |

| | |
|---|---|
| Name: | Matt Hood |
| Project Role: | Study Coordinator/Informatics |
| Research Identifier: | 3 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Mr. Hood has worked with IRB submissions, HRPO submissions, database development/maintenance, |

| | |
|---|---|
| | participant recruitment, screening, conducting evaluation visits, retention, and scheduling, prosthetic clinic communication and scheduling. |
| Name: | William Mihalko, MD, PhD |
| Project Role: | Co-Investigator |
| Research Identifier: | 4 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Dr. Mihalko is fulfilling the role of co-investigator overseeing intervention safety and adverse event reporting as outlined in the SOW. |
| Name: | Catherine Womack, MD |
| Project Role: | Co-Investigator |
| Research Identifier: | 5 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Dr. Womack is fulfilling the role of co-investigator adjudicating any participant eligibility determinations in which medical history and/or current health habits (e.g. medication and/or substance abuse, depression status, etc) are in question. |
| Name: | Kunal Singhal, PhD, PT |
| Project Role: | Co-Investigator |
| Research Identifier: | 6 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Dr. Singhal is continuing to fulfill his the role of co-investigator providing the physical therapy intervention for participants and insuring consistency in delivery of the intervention protocol. Additionally, as of March 1, 2017, Dr. Singhal has also assumed the primary "Intervention PI" duties previously assigned to Dr. Zucker-Levin, as outlined in the revised SOW, following her departure from the University as a full-time employee. |
| Name: | E Shannon Hughes, PT |
| Project Role: | Co-Investigator |
| Research Identifier: | 7 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Ms. Hughes is fulfilling the role of co-investigator performing the physical therapy evaluations and other primary outcome measurements during the in-person evaluation visits (baseline, 3-month and 6-month) the as outlined in the SOW. |

| | |
|---|---|
| Name: | Jim Wan, PhD |
| Project Role: | Co-Investigator |
| Research Identifier: | 8 |
| Nearest person month worked: | 12 |
| Contribution to Project: | Dr. Wan is fulfilling the co-investigator role as Statiscian outlined in the SOW. |

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

Effective March 1, 2017, Dr. Audrey Zucker-Levin (Joint-PI) left the University as a full-time employee. This change in personnel was reported and a revised SOW submitted March 1, 2017. As a result of this personnel change, Dr. Richey (Joint-PI) has assumed the majority of Dr. Zucker-Levin's duties and Dr. Singhal (Co-I), being a physical therapist like Dr. Zucker-Levin, has assumed her primary "Intervention PI" duties. Dr. Zucker-Levin remains on the project contributing up to 10% effort.

**PLEASE NOTE:** Repeated requests have been made, including official documentation submitted via the university official signatory authority, to remove Dr. Zucker-Levin (azuckerlevin@uthsc.edu) as the primary contact for this award and make Dr. Richey (prichey@uthsc.edu) the primary contact. To date, that change request still has not been executed and correspondence from CDMRP continues to be directed to Dr. Zucker-Levin. **PLEASE CHANGE THE PRIMARY CONTACT FOR THIS AWARD TO DR. RICHEY IMMEDIATELY.** All correspondence regarding this award should be directed to Dr. Phyllis Richey at prichey@uthsc.edu.

**What other organizations were involved as partners?**

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*
*Provide the following information for each partnership:*
*Organization Name:*
*Location of Organization: (if foreign location list country)*
*Partner's contribution to the project (identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

| | |
|---|---|
| Organization Name: | CFI Prosthetics and Orthotics |
| Location of Organization: | Memphis, TN |
| Partner's contribution to the project: | Partner Prosthetic Clinic |
| Financial support: | None |
| In-kind support: | None |
| Facilities: | Prosthetic fitting and training sessions for intervention group participants |
| Collaboration: | Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures |
| Personnel exchanges: | None |
| Other: | None |
| Organization Name: | Human Technology Prosthetics and Orthotics |
| Location of Organization: | Memphis, TN |
| Partner's contribution to the project: | Partner Prosthetic Clinic |
| Financial support: | None |
| In-kind support: | None |
| Facilities: | Prosthetic fitting and training sessions for intervention group participants |
| Collaboration: | Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures |
| Personnel exchanges: | None |
| Other: | None |
| Organization Name: | Precision Prosthetics, Inc. |
| Location of Organization: | Memphis, TN |
| Partner's contribution to the project: | Partner Prosthetic Clinic |
| Financial support: | None |
| In-kind support: | None |
| Facilities: | Prosthetic fitting and training sessions for intervention group participants |
| Collaboration: | Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures |
| Personnel exchanges: | None |
| Other: | None |
| Organization Name: | Spears Prosthetics and Orthotics |
| Location of Organization: | Memphis, TN |
| Partner's contribution to the project: | Partner Prosthetic Clinic |
| Financial support: | None |
| In-kind support: | None |
| Facilities: | Prosthetic fitting and training sessions for intervention group participants |
| Collaboration: | Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures |
| Personnel exchanges: | None |
| Other: | None |

| | |
|---|---|
| Organization Name: | Disabled American Veterans (DAV) |
| Location of Organization: | Tennessee |
| Partner's contribution to the project: | Assisting with recruitment |
| Financial support: | None |
| In-kind support: | None |
| Facilities: | None |
| Collaboration: | Dissemination study informational materials to potential participants |
| Personnel exchanges: | None |
| Other: | None |

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:**

Not Applicable

**QUAD CHARTS:**

Attached

**9. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Attached

# The effect of a microprocessor prosthetic foot on function, safety and quality of life in trans-tibial amputees who are limited community ambulators.

**PI's:** Richey, P.A. & Zucker-Levin, A.R. **Org:** Tennessee, University of Health Science Center **Award Amount:** $1,492,955

**Background**: The vast majority (62%) of service member and veteran amputees are over 65 years of age and function as limited community ambulators at high risk for tripping and falling possibly due to the limited function of the traditional prosthesis they are prescribed. We hypothesize that a microprocessor controlled prosthetic foot would improve functional performance, ambulatory safety and quality of life in these low level functioning veterans.

**Study Aims: Primary (3)**

To determine if a microprocessor controlled prosthetic foot, with greater range of motion and active power, will improve functional performance (SA:1), Ambulatory Safety (SA:2), and Quality of Life (SA:3) in trans-tibial amputees who function as limited community ambulators.

**Secondary Aim:**

To determine if a microprocessor controlled prosthetic foot, with greater range of motion and active power, will improve prosthesis-related QOL in trans-tibial amputees who function as limited community ambulators.

## 3 Year Project Timeline

| Activity | Year 1 | Year 2 | Year 3 |
|---|---|---|---|
| Process/Approvals | | | |
| Recruitment/Evaluation | | | |
| Intervention | | | |
| 3-month follow up | | | |
| 6-month follow up | | | |
| Analysis/Dissemination | | | |

**Updated:** (September 30, 2017)

## Goals/Milestones (N=54 except where noted)

**Year 1** –

☑ Define processes/Obtain all approvals for safety and compliance.
☑ Begin participant recruitment and baseline evaluation including randomization into intervention and comparison groups
☑ Begin Prosthetic Fitting Period (2 weeks) intervention group (N=27)
☑ Begin 4 week Physical Therapy sessions for both groups
☑ Begin 3 month follow up visits
☑ Begin Accommodation phase 1 with weekly phone visits

**Year 2** –

❑Complete participant recruitment and evaluation
❑Complete Prosthetic Fitting Period and Physical Therapy Sessions
☑ Continue 3 month and begin 6 month follow up visit
❑Complete accommodation phase 1
☑ Begin accommodation phase 2 with weekly phone visits

**Year 3** –

❑Complete 3 and 6 month follow up visits
❑Complete accommodation phase 2
❑Complete data analyses
❑Disseminate findings in journal and conference venues